5 510(k) Summary of Safety and Effectiveness

K080351

APR 22 2008

SUBMITTER: Dexela Limited

CONTACT PERSON: Michael Henry

DATE PREPARED: 31 January, 2008

DEVICE TRADE NAME: DexTop Mammography Workstation

COMMON NAME: DexTop Mammography Workstation

CLASSIFICATION NAME: Picture Archiving and Communication System

PREDICATE DEVICE(S): General Electric Medical Systems: Seno Advantage (K033400)

DEVICE DESCRIPTION:

The DexTop Mammography Workstation is a software product, which runs on a high end personal computer, for the purpose of non-invasive multi-modality review. It provides very high performance viewing, processing and analysis of multimodality two and three dimensional, as well as planar medical image data.

The DexTop Mammography Workstation receives digital image data from various sources including a variety of diagnostic imaging systems, Hospital PACS, Electronic media and local file systems.

The architecture of the DexTop Workstation means that it can be deployed as a central base station with satellite workstations all using the same user configuration store and image data.

The Dexela DexTop Mammography Workstation supports the following image network communications:

- Standard 10/100/1000 Base-T Ethernet protocols
- DICOM 3.0 Storage SCP and Query/Retrieve SCU.
- TCP/IP network layer

The hardware configuration used with the software typically will include a PC, a single standard color monitor, a multi-function keypad (for increased productivity), and two high resolution monitors for mammographic image review.
See the following table.

Component	Quantity
SYSTEM: Multi-core (>2) 64-bit processor	1
Memory: Minimum 2GB RAM	NA
STORAGE: DVD Drive SONY DDU1615 or equivalent	1
RAM: Minimum 80 GB (MAXTOR ATLAS SCSI drive or equiv)	NA
DISPLAYS: Any HIPAA approved display monitors	1 or 2 depending on configuration
PERIPHERALS: Standard keyboard Standard mouse X-KEYS SE USB – LCD keypad	1 each
SOFTWARE: Windows XP Professional X64 Dexela Mammography Workstation Software	1 each

INDICATION FOR USE:

The DexTop Mammography Workstation is a mammography review workstation software package, which provides very high performance viewing, processing and analysis of multimodality two and three dimensional, as well as planar, medical image data.

The DexTop Workstation is designed to assist the radiologist in conducting screening and primary diagnosis through flexible, fast and efficient image hanging and processing of multimodality soft-copy images with special emphasis and optimization for mammography.

When interpreted by a skilled physician, this software provides information that may be useful in screening and diagnosis. However, the final judgment must rely on the knowledge and skill of the physician.

TECHNOLOGICAL CHARACTERISTICS:

Hardware	
64 bit Windows Operating System	More memory for larger data sets and increase speed of workflow
Multi-core processor	Makes full use of new multi core CPUs to maximize throughput
Remote workstation configuration	Multiple workstations can view the same data.
Easy to use shortcut keypad	Shortcut keys to often used functions are presented on a separate keypad for ease of use
Communications	
DICOM	DICOM compliant communications
Software	
Modalities	MG,MR,CR,US
Multi-vendor imaging	Fully IHE and DICOM compliant image display allows any vendor image to be displayed correctly
Window centre and width adjustment	Window centre and width can be freely adjusted

Hardware	
	for any image maintaining the predefined curve if it exists
Use of imbedded VOI LUTs	Correct implementation of the DICOM LUTS imbedded in the image file, including the ability for the user to adjust the image maintain the same curve
Linear and Sigmoid LUTs	Switch between the use of a linear or a sigmoid curve for the display of gray scale images
Pull-scale function	Function allowing the user to focus on a specific area with regard to window centre and width
User specific window center and width	The system can remember the individual's preference for an image with regard to changes made to its default window centre and width
Highly flexible patient and technical information display	The user can specify which pieces of patient and technical information should appear on which screen
XML based annotation	Allows the radiologist to annotate the images in a very flexible way. The annotation can be hidden and deleted as required
Flip, Zoom, Invert and Pan	The images can be manipulated on screen in all the usual ways
Tiling	Images series or planar images can be tiled to the screen allowing some or all of the frames to viewed at the same time.
Shutter-View	A type of shutter view of the image where two synchronized images have a mask overlaid so only the same small portion of each image is visible.
1:1 view	Display of the image data at one pixel per image data.
Life-size view	Display of the image at life size
Magnifying glass	A zoomed in portion of the image at the current cursor position
Hot lamp / Bright Light	A portion of the image is displayed as if a brighter light had been applied to that area of the screen.
CLAHE and Un-sharp Mask	Image processing techniques can be applied to sharpen and equalize the images
Highly configurable hanging	Hanging protocols are designed per user with unlimited categories and limitless flexibility with respect to screen use and positioning
Smart-Merge Protocol	Specific technology that brings together user preferences from different aspects of film type and screen use and combines them to form a new hanging from images that are only loosely specified.
DICOM printing	DICOM printing
Data export	Export data to CD or for presentations

NON-CLINICAL REQUIREMENTS TEST:

The non-clinical testing for the DexTop Workstation includes performance of system requirements testing according to the Software Testing Strategy and following the test cases as defined in the Software Requirements Test Specification Document.

CONCLUSIONS:

Software Development for the DexTop workstation has been performed in accordance with the Software Development Plan and following the guidance of the Dexela Design and Development Procedures, and which includes, in addition to other documents, a Product Risk Analysis, Software Requirements, Design and Development Plan, detailed Architecture documents , Testing Strategy, and Software Requirements Test Specification. Therefore Dexela is confident that the system as developed will perform according to the specifications detailed in the User Requirements Specification and System Requirements Specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

Dexela, Ltd.
% Mr. Barry Sall, RAC
Principal Consultant
Parexel Consulting
200 West St.
WALTHAM MA 02451

Re: K080351
Trade/Device Name: Dexela DexTop Mammography Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 28, 2008
Received: March 31, 2008

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K080351

Device Name: Dexela DexTop Mammography Workstation

The DexTop Mammography Workstation is a mammography review workstation software package, which provides very high performance viewing, processing and analysis of multimodality two and three dimensional, as well as planar, medical image data.

The DexTop Workstation is designed to assist the radiologist in conducting screening and primary diagnosis through flexible, fast and efficient image hanging and processing of multimodality soft-copy images with special emphasis and optimization for mammography.

Dexela DexTop Mammography Workstation will display the full fidelity DICOM image in a non-compressed format. Lossy compressed mammography images and digitized film screen images must not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 megapixel resolution and meets other technical specifications reviewed and accepted by the FDA

When interpreted by a skilled physician, this software provides information that may be useful in screening and diagnosis. However, the final judgment must rely on the knowledge and skill of the physician.

The device will display only DICOM "For Presentation" images for primary image diagnosis. The device does not perform any image processing (except simple manipulation such as gray scale changes by window level and window width) of the proprietary image processing algorithm of the FFDM manufacturers.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080351